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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,269	09/23/1999	RANDALL S. ALBERTE	CEA-004.01	9298

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EXAMINER

YAMNITZKY, MARIE ROSE

ART UNIT	PAPER NUMBER
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1774

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,269

Applicant(s)

ALBERTE ET AL.

Examiner

Marie R. Yamnitzky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,9-24,26-30,32-39,43,44,47-63,66,68,70-74 and 89 is/are pending in the application.
- 4a) Of the above claim(s) 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,9-24,26-30,32,33,38,39,43,44,47-63,66,68,70-74 and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. This Office action is in response to applicant's amendment received October 05, 2005, which amends claims 1, 6, 10, 11, 14-16, 18-20, 23, 24, 26, 30, 32, 33, 39, 48, 49, 51, 54, 55, 57, 58 and 70, and cancels claims 4, 25, 42, 90 and 91.

Claims 1, 5, 6, 9-24, 26-30, 32-39, 43, 44, 47-63, 66, 68, 70-74 and 89 are pending.

2. This Office action is also in response to the Rule 132 Declaration of Randall S. Alberte received October 05, 2005.

3. The rejection of claims 51 and 55 under 35 U.S.C. 112, 2nd paragraph, as set forth in the Office action mailed April 05, 2005, is overcome by applicant's amendment.

4. The claims remain subject to an election of species. In the reply filed on May 14, 2001, applicant elected the species of a compound of general structure 1, applied to the surface of a medical device, wherein X represents -OH, Y represents O and Z represents an optionally substituted aryl. Of the pending claims, claims 1, 5, 6, 9-24, 26-30, 32, 33, 38, 39, 43, 44, 47-63, 66, 68, 70-74 and 89 read on the elected species. (Claims dependent from claim 39 which further limit the article are all considered to read on the elected species since, for claim 39 and dependents, the article pertains to the intended use of the claimed coating.)

Claims 34-37 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 14, 2001.

5. Claims 1, 5, 6, 9-24, 26-30, 32, 33, 38, 39, 43, 44, 47-63, 66, 68, 70-74 and 89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations added at the end of independent claims 1 and 39 regarding the coating (“wherein the coating is an aqueous...or silicone coating”) are not fully supported by the application as originally filed. Applicant states that support for the amendment can be found on page 14 of the specification and in the examples. The claim language is not the same as in the original disclosure, and therefore support for some portions of the claim language is not clear. For example, while page 14 discloses phenolic resins, epoxy resin, polyamide resins and vinyl resins, the present claims generically recite “resin” (which encompasses resins other than those specifically named on page 14) and do not limit “vinyl”, “phenolic”, “epoxy” or “polyamide” to resins. As another example, while page 14 recites “acrylate polymers”, page 14 does not recite “acrylic”, and the claims allow the coating to be an “acrylic” or “acrylate” coating.

6. Claims 1, 5, 6, 9-24, 26-30, 32, 33, 38, 39, 43, 44, 47-63, 66, 68, 70-74 and 89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific systems and coatings demonstrated by the examples to have anti-fouling capabilities as required by the present claims, does not reasonably provide enablement for a system of the scope as claimed in present claim 1 and dependents or a coating of the scope as claimed in present

claim 39 and dependents wherein the terms “system”, “biofilm resistant surface” and “coating” encompass numerous structures/compositions, the term “anti-fouling” encompasses a variety of possible modes of action against numerous possible organisms, and the general structure for the compound as defined in the independent claims and some of the dependent claims encompasses numerous compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In light of the specification, the terms “system” and “biofilm resistant surface” encompass a very large group of articles/surfaces including such disparate “systems” as food processing equipment, heart valves, tampons and toilets. For example, see page 5, lines 8-17, p. 9, l. 5-7, p. 15, l. 16, p. 15, l. 26-p. 16, l. 2, p. 16, l. 23-p. 17, l. 10, p. 18, l. 6-14, p. 18, l. 20-p. 19, l. 10 and p. 25, l. 9-p. 26, l. 27. In light of claim 29, it appears that the presently claimed system even encompasses plants.

The term “coating” encompasses a variety of compositions comprising components necessary to provide a coating as defined in the last three lines of independent claims 1 and 39, and comprising a compound of general structure 1.

In light of the specification, an “anti-fouling” compound is one that impairs, inhibits, prevents or retards the attachment and/or growth of organisms such as bacteria, fungi, viruses and protists (e.g. see p. 12, l. 16-18, p. 13, l. 23-24 and p. 18, l. 15-19).

The compounds as defined in the present independent claims and some of the dependent claims encompass numerous compounds.

Accordingly, the present system claims encompass objects as diverse as food processing equipment, heart valves, tampons and toilets comprising a composition comprising components necessary to provide a coating as defined in the last three lines of independent claim 1, and the present coating claims encompass any composition comprising components necessary to provide a coating as defined in the last three lines of independent claim 39, wherein the composition also comprises at least one compound selected from numerous compounds encompassed by the general structures defined in the claims that would impair, inhibit, prevent or retard the attachment and/or growth of organisms such as bacteria, fungi, viruses and/or protists. Clearly, the claims are extremely broad.

The present specification provides data demonstrating anti-fouling capabilities of only a few compounds within the scope of the present claims, and demonstrates the anti-fouling characteristics of only a few systems and coatings. The limited data presented in the specification are insufficient to demonstrate any predictability with respect to how each of the numerous compounds encompassed by the general structures defined in the present claims would function in an anti-fouling capacity against any one of thousands of possible organisms such as bacteria, fungi, viruses and/or protists if used in/on any one of the numerous possible diverse surfaces/ systems contemplated by the present specification and encompassed by the present claims. Accordingly, it is the examiner's position that it would require undue experimentation on the part of one of ordinary skill in the art at the time of the invention to make and use the invention commensurate in scope with the present claims.

Data pertaining to four compounds are set forth in the specification. Three of the tested compounds (zosteric acid, methyl sulfate and octyl sulfate) do not meet the limitations of the anti-fouling compound required for any of the pending claims. Only one of the tested compounds (4-t-pentylphenyl chlorosulfate) meets the limitations of the anti-fouling compound required for each of the pending claims, and the single example presented for that compound pertains to sea urchin fertilization.

Even in the case where the compounds required for the claimed system or coating are limited to a relatively small number of compounds, the claims are still broader in scope than the enabling scope of the disclosure because limitations such as the "effective amount" are defined only in reference to a variety of potential applications. It is the examiner's position that the data presented in the specification are insufficient to demonstrate predictability even with respect to the limited number of compounds defined, for example, in claims 24 and 62 (the system and coating claims that are most limited with respect to the anti-fouling compound), given the broad scope of systems, biofilm resistant surfaces, coating formulations, and anti-fouling capabilities encompassed by the present claim terminology. 4-t-pentylphenyl chlorosulfate is the only compound tested in the specification that is within the scope of the twelve compounds defined by claims 24 and 62. It is not clear that the activity of 4-t-pentylphenyl chlorosulfate towards sea urchin fertilization is representative of all systems encompassed by claim 24 and all coatings encompassed by claim 62, or that the full scope of systems and coatings encompassed by these claims can be determined without undue experimentation based on the single sea urchin fertilization example using 4-t-pentylphenyl chlorosulfate.

7. Applicant's arguments filed October 05, 2005 have been fully considered, along with the Rule 132 declaration of Randall S. Alberte filed October 05, 2005, but they are not persuasive.

The examiner has considered the data presented in the original disclosure, the data presented in the Rule 132 declaration, and applicant's arguments.

It is not clear from the Rule 132 declaration whether the data presented in the declaration pertain to tests carried out by the declarant and/or under the declarant's supervision, and does not indicate when the tests were conducted. It is not clear that the declaration pertains to what one skilled in the art knew at the time of the filing of the application.

The exact compositions of the coatings tested in the declaration are also not specified. It is not clear why there are two different sets of data for each of the five FendoffTM series compounds in the table on page 4 of the declaration; does each data set represent a different composition? Any trends that might be useful in predicting, for example, different coating compositions that comprise an effective amount of an anti-fouling compound are not readily apparent from the declaration.

Applicant must demonstrate by argument and/or evidence that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time of the invention. While applicant may provide a declaration demonstrating that the claimed invention works, the experiments of the declaration must have used the guidance in the specification as filed and what was well known to one of skill in the art, and must bear a reasonable correlation to the scope of the claimed invention.

The claims have been narrowed with respect to the scope of compounds covered by general structure 1, and have been narrowed with respect to the composition of the coating. However, general structure 1 as defined in the independent claims still covers a large variety of compounds, and the additional compositional limitations required by the last three lines of the independent claims provide for a wide variety of materials.

The limited number of examples set forth in the specification are insufficient to demonstrate that the anti-fouling capabilities of the various compounds towards the numerous organisms which might foul a system/surface are sufficiently predictable such that undue experimentation would not be required to determine the scope of systems encompassed by claim 1 and dependents, and the scope of coatings encompassed by claim 39 and dependents.

Likewise, the data presented in the declaration is not considered to bear a reasonable correlation to the scope of the claimed invention. For example, the eight compounds tested are compounds of general structure 1 wherein Y is O. There is no evidence of record to demonstrate that one of ordinary skill in the art at the time of the invention would expect the corresponding compounds in which Y is S or Se to have the same properties. Further the eight compounds tested are compounds of general structure 1 wherein Z is an alkyphenyl or phenylalkylphenyl group, and represent only a small subset of compounds within the scope of the present claims.

Applicant argues that it is the $-YS(O)_2X$ moiety that imparts the anti-fouling properties to the coating, and compounds having this moiety can tolerate a wide variety of Z moieties and still be effective at preventing biofouling. However, the data presented in the specification and the declaration demonstrate that relatively small changes in the Z moiety have an impact on anti-

fouling capabilities. There is no evidence of record to demonstrate the effect that one might expect/predict for Z moieties other than those for which data are presented.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 39, 43, 44, 47-63, 66, 68, 70-74 and 89 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34 and 37-39 of copending Application No. 09/406,184. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The examiner notes that claims 34 and 37-39 were finally rejected in an Office action mailed September 09, 2005. A proposed amendment was received December 12, 2005 and has

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not yet been acted upon by the examiner to which the '184 application is docketed (an examiner other than the present examiner). This provisional obviousness-type double patenting rejection is applied regardless of whether the proposed amendment received December 12, 2005 is entered.

The present claims and the copending claims claim overlapping subject matter, regardless of whether the proposed amendment is entered in the copending application. (If the proposed amendment is entered in the copending application, copending independent claim 34 and present independent claim 39 will be even closer in scope than if the proposed amendment is not entered.) Copending independent claim 34 is narrower than present independent claim 39 with respect to the definition of X and Y, but broader than present claim 39 with respect to the definition of Z. The present and copending dependent claims would lead one of ordinary skill in the art to anti-fouling compounds of structure I that are the same. For example, copending claim 39 provides for seven specific compounds of structure I, and present claim 62 provides for twelve specific compounds of structure I. Six of the compounds of copending claim 39 and present claim 62 are the same compounds. The copending claims are also narrower than the present claims with respect to the description as set forth in the last three lines of present claim 39, but all possibilities for the coating as recited in copending claim 34 are recited in present claim 39.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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10. Applicant is advised that should claim 1 be found allowable, claim 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, and should claim 39 be found allowable, claim 48 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. Any inquiry concerning this communication should be directed to Marie R. Yamnitzky at telephone number (571) 272-1531. The examiner works a flexible schedule but can generally be reached at this number from 6:30 a.m. to 4:00 p.m. Monday, Tuesday, Thursday and Friday, and every other Wednesday from 6:30 a.m. to 3:00 p.m.

The current fax number for all official faxes is (571) 273-8300. (Unofficial faxes to be sent directly to examiner Yamnitzky can be sent to (571) 273-1531.)

MRY
January 09, 2006



MARIE YAMNITZKY
PRIMARY EXAMINER

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